IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

RITA FOHNE,	)	
	)	
Plaintiff,	)	
	)	
vs.	)	Case No. 07-cv-284
	)	
PFIZER INC.,	)	
	)	Jury Trial Demanded
Defendant.	)	

ANSWER, ADDITIONAL DEFENSES, AND JURY DEMAND OF DEFENDANT PFIZER INC.

COMES NOW the Defendant, Pfizer Inc. ("Defendant"), and for its answer and affirmative defenses to Plaintiff's Complaint ("Complaint"), states as follows:

1. Defendant admits that Plaintiff is a resident of Lebanon, Illinois. Defendant admits that Plaintiff seeks damages, but denies that there is any legal or factual basis for the purported causes of action and/or damages sought by Plaintiff. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 1 concerning Plaintiff's use of Bextra® and therefore denies the same. Defendant denies all remaining or inconsistent allegations contained in Paragraph 1 of Plaintiff's Complaint.

2. Defendant admits that Pfizer is a corporation which is incorporated in the State of Delaware and is registered to do business in Illinois. Defendant admits that, during certain times, Pfizer marketed and co-promoted Bextra®.

3. Paragraph 3 contains legal conclusions to which no response is needed. To the extent a response is deemed necessary, Defendant denies the allegations contained in Paragraph 3 of Plaintiff's Complaint.

4. Paragraph 4 contains legal conclusions to which no response is needed. To the extent a response is deemed necessary, Defendant denies the allegations contained in Paragraph 3 of Plaintiff's Complaint.

5. Paragraph 5 contains legal conclusions to which no response is needed. To the extent a response is deemed necessary, Defendant denies the allegations contained in Paragraph 3 of Plaintiff's Complaint.

6. Paragraph 6 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendant admits that it has duties as are imposed by law, but denies that it has breached any such duties. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant denies all remaining or inconsistent allegations contained in Paragraph 6 of Plaintiff's Complaint.

7. Paragraph 7 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendant admits that it has duties as are imposed by law, but denies that it has breached any such duties. Defendant denies all remaining or inconsistent allegations contained in Paragraph 7 of Plaintiff's Complaint, and specifically denies any "fraudulent concealment."

8. Paragraph 8 states legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendant denies the allegations contained in Paragraph 8 of Plaintiff's Complaint and specifically denies that it committed torts, made material omissions and representations, and breached warranties.

9. Paragraph 9 states a legal conclusion to which no response is required. To the extent a response is deemed necessary, Defendant denies the allegations contained in Paragraph 9 of Plaintiff's Complaint.

10. Defendant admits that, during certain times, Pfizer marketed and co-promoted Bextra®. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant denies all remaining or inconsistent allegations contained in Paragraph 10 of Plaintiff's Complaint.

11. Defendant admits that, during certain times, it marketed and co-promoted Bextra®. Defendant denies all remaining or inconsistent allegations contained in Paragraph 11 of Plaintiff's Complaint.

12. Defendant denies the allegations contained in Paragraph 12 of Plaintiff's Complaint. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

13. Defendant admits the FDA approved Bextra on November 16, 2001. Defendant states, as indicated in the package insert approved by the FDA, that Bextra® was approved by the FDA for relief of the signs and symptoms of osteoarthritis and adult rheumatoid arthritis, and for the treatment of primary dysmenorrhea. Defendant admits that, during certain times, Pfizer marketed and co-promoted Bextra®. Defendant further states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant denies all remaining or inconsistent allegations contained in Paragraph 13 of Plaintiff's Complaint.

14. Defendant denies the allegations contained in Paragraph 14 of Plaintiff's Complaint. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

15. Defendant lacks knowledge or information sufficient to form a belief as to the truth of the allegations contained in Paragraph 15 concerning Plaintiff's prescription or use of Bextra® and therefore denies the same. Defendant denies that Bextra® caused Plaintiff's alleged heart attack and cardiovascular injury, and denies all remaining or inconsistent allegations contained in Paragraph 15 of Plaintiff's Complaint.

16. Defendant denies the allegations contained in Paragraph 16 of Plaintiff's Complaint and specifically denies that its conduct was "wrongful."

17. Defendant admits that, during certain times, it marketed and co-promoted Bextra®. Defendant denies all remaining or inconsistent allegations contained in Paragraph 17 of Plaintiff's Complaint.

18. Defendant denies the allegations contained in Paragraph 18 of Plaintiff's Complaint. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

19. Defendant denies the allegations contained in Paragraph 19 of Plaintiff's Complaint.

20. Defendant denies the allegations contained in Paragraph 20 of Plaintiff's Complaint. Defendant states that the potential effects of Bextra® were and are adequately

described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

21. Defendant incorporates each and every admission and denial set forth in Paragraphs 1 through 20 as though fully rewritten herein.

22. Defendant admits that Plaintiff seeks damages, but denies that there is any legal or factual basis for the purported causes of action and/or damages sought by Plaintiff. Defendant denies the allegations contained in Paragraph 22 of Plaintiff's Complaint and specifically denies that Bextra® is or was "defectively designed."

23. Defendant denies the allegations contained in Paragraph 23 of Plaintiff's Complaint and specifically denies that Bextra® is or was "defectively marketed." Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

24. Defendant denies the allegations contained in Paragraph 24 of Plaintiff's Complaint. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information.

25. Defendant denies the allegations contained in Paragraph 25 of Plaintiff's Complaint.

RESPONSE TO UNNUMBERED "WHEREFORE" PARAGRAPH IN COUNT ONE

Defendant denies that there is any legal or factual basis which entitles Plaintiff to recover any of the relief requested in the prayer for relief in the unnumbered "WHEREFORE" paragraph in Count One of the Complaint.

26. Defendant incorporates each and every admission and denial set forth in Paragraphs 1 through 25 as though fully rewritten herein.

27. Defendant denies the allegations contained in Paragraph 27 of Plaintiff's Complaint. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant further states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information.

28. Defendant denies the allegations contained in Paragraph 28 of Plaintiff's Complaint. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant further states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information.

29. Defendant denies the allegations contained in Paragraph 29 of Plaintiff's Complaint.

30. Defendant denies the allegations contained in Paragraph 30 of Plaintiff's Complaint. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant further states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information.

31. Defendant denies the allegations contained in Paragraph 31 of Plaintiff's Complaint. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

32. Defendant denies the allegations contained in Paragraph 32 of Plaintiff's Complaint. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

RESPONSE TO UNNUMBERED "WHEREFORE" PARAGRAPH IN COUNT TWO

Defendant denies that there is any legal or factual basis which entitles Plaintiff to recover any of the relief requested in the prayer for relief in the unnumbered "WHEREFORE" paragraph in Count Two of the Complaint, including subparts A through D.

33. Defendant incorporates each and every admission and denial set forth in Paragraphs 1 through 32 as though fully rewritten herein.

34. Defendant denies the allegations contained in Paragraph 34 of Plaintiff's Complaint.

35. Paragraph 35 contains legal conclusions to which no response is required. To the extent a response is deemed necessary, Defendant admits that it has duties as are imposed by law, but denies that it has breached any such duties. Defendant denies all remaining or inconsistent allegations contained in Paragraph 35, including subparts (a) through (p). Defendant specifically denies that Bextra® is "dangerous," "unsafe," or "highly harmful." Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved

prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant further states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information.

36. Defendant denies the allegations contained in Paragraph 36 of Plaintiff's Complaint.

RESPONSE TO UNNUMBERED "WHEREFORE" PARAGRAPH IN COUNT THREE

Defendant denies that there is any legal or factual basis which entitles Plaintiff to recover any of the relief requested in the prayer for relief in the unnumbered "WHEREFORE" paragraph in Count Three of the Complaint.

37. Defendant incorporates each and every admission and denial set forth in Paragraphs 1 through 36 as though fully rewritten herein.

38. Defendant admits that, during certain times, it marketed and co-promoted Bextra®. Defendant denies all remaining or inconsistent allegations contained in Paragraph 38 of Plaintiff's Complaint.

39. Paragraph 39 contains a legal conclusion to which no response is needed. To the extent a response is deemed necessary, Defendant admits that it has such duties as are imposed by law, but denies that it has breached any such duty. Defendant denies all remaining or inconsistent allegations contained in Paragraph 39 of Plaintiff's Complaint.

40. Paragraph 40 contains legal conclusions to which no response is needed. To the extent a response is deemed necessary, Defendant admits that it has such duties as are imposed by law, but denies that it has breached any such duties. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

Defendant further states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information. Defendant denies all remaining or inconsistent allegations contained in Paragraph 40 of Plaintiff's Complaint.

41. Defendant denies the allegations contained in Paragraph 41 of Plaintiff's Complaint.

42. Defendant denies the allegations contained in Paragraph 42 of Plaintiff's Complaint.

RESPONSE TO UNNUMBERED "WHEREFORE" PARAGRAPH IN COUNT FOUR

Defendant denies that there is any legal or factual basis which entitles Plaintiff to recover any of the relief requested in the prayer for relief in the unnumbered "WHEREFORE" paragraph in Count Four of the Complaint.

43. Defendant incorporates each and every admission and denial set forth in Paragraphs 1 through 42 as though fully rewritten herein.

44. Defendant denies the allegations contained in Paragraph 44 of Plaintiff's Complaint. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information.

45. Defendant denies the allegations contained in Paragraph 45 of Plaintiff's Complaint, including subparts (a) through (f), except to admit that, during certain times, Defendant marketed and co-promoted Bextra®. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant further states that Bextra® was and is safe and effective when used in accordance with its FDA-

approved prescribing information. Defendant denies all remaining or inconsistent allegations contained in Paragraph 45 of Plaintiff's Complaint.

46. Defendant admits that, during certain times, Pfizer marketed and co-promoted Bextra®. Defendant denies all remaining or inconsistent allegations contained in Paragraph 46 of Plaintiff's Complaint.

47. Defendant denies the allegations contained in Paragraph 47 of Plaintiff's Complaint. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant further states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information.

48. Defendant denies the allegations contained in Paragraph 48 of Plaintiff's Complaint. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant further states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information.

49. Defendant denies the allegations contained in Paragraph 49 of Plaintiff's Complaint. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant further states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information.

50. Defendant denies the allegations contained in Paragraph 50 of Plaintiff's Complaint, including subparts (a) through (c). Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant further states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information.

51. Defendant denies the allegations contained in Paragraph 51 of Plaintiff's Complaint. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant further states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information.

52. Defendant denies the allegations contained in Paragraph 52 of Plaintiff's Complaint.

RESPONSE TO UNNUMBERED "WHEREFORE" PARAGRAPH IN COUNT FIVE

Defendant denies that there is any legal or factual basis which entitles Plaintiff to recover any of the relief requested in the prayer for relief in the unnumbered "WHEREFORE" paragraph in Count Five of the Complaint.

53. Defendant incorporates each and every admission and denial set forth in Paragraphs 1 through 52 as though fully rewritten herein.

54. Defendant denies the allegations contained in Paragraph 54 of Plaintiff's Complaint. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information.

55. Defendant denies the allegations contained in Paragraph 55 of Plaintiff's Complaint and specifically denies any "false" representations or "omissions." Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information.

56. Defendant denies the allegations contained in Paragraph 56 of Plaintiff's Complaint and specifically denies any "false" representations or "omissions." Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information.

57. Defendant denies the allegations contained in Paragraph 57 of Plaintiff's Complaint and specifically denies any "false" representations or "omissions."

58. Defendant denies the allegations contained in Paragraph 58 of Plaintiff's Complaint and specifically denies any "fraudulent conduct."

RESPONSE TO UNNUMBERED "WHEREFORE" PARAGRAPH IN COUNT SIX

Defendant denies that there is any legal or factual basis which entitles Plaintiff to recover any of the relief requested in the prayer for relief in the unnumbered "WHEREFORE" paragraph in Count Six of the Complaint.

59. Defendant incorporates each and every admission and denial set forth in Paragraphs 1 through 58 as though fully rewritten herein.

60. Defendant denies the allegations contained in Paragraph 60 of Plaintiff's Complaint. Defendant states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information.

61. Defendant denies the allegations contained in Paragraph 61 of Plaintiff's Complaint. Defendant states that the potential effects of Bextra® were and are adequately

described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

62. Defendant denies the allegations contained in Paragraph 62 of Plaintiff's Complaint, except to admit that, during certain times, Defendant marketed and co-promoted Bextra®. Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law.

63. Defendant denies the allegations contained in Paragraph 63 of Plaintiff's Complaint, and specifically denies any "false" representations.

64. Defendant denies the allegations contained in Paragraph 64 of Plaintiff's Complaint.

65. Defendant denies the allegations contained in Paragraph 65 of Plaintiff's Complaint.

66. Defendant denies the allegations contained in Paragraph 66 of Plaintiff's Complaint, and specifically denies any "misrepresentation."

RESPONSE TO UNNUMBERED "WHEREFORE" PARAGRAPH IN COUNT SEVEN

Defendant denies that there is any legal or factual basis which entitles Plaintiff to recover any of the relief requested in the prayer for relief in the unnumbered "WHEREFORE" paragraph in Count Seven of the Complaint

67. Defendant incorporates each and every admission and denial set forth in Paragraphs 1 through 66 as though fully rewritten herein.

68. Defendant admits that Plaintiff seek damages, but denies that there is any legal or factual basis for the purported causes of action and/or damages sought by Plaintiff. Defendant

denies all remaining or inconsistent allegations contained in Paragraph 68 of Plaintiff's Complaint.

69. Defendant denies that Paragraph 69 of Plaintiff's Complaint contains an accurate partial quote of the cited statute. Defendant denies all remaining or inconsistent allegations contained in Paragraph 69 of Plaintiff's Complaint.

70. Paragraph 70 states a legal conclusion to which no response is required. To the extent a response is deemed necessary, Defendant denies the allegations contained in Paragraph 70 of Plaintiff's Complaint and specifically denies any "false" or "misleading" "misrepresentations" or "omissions." Defendant states that the potential effects of Bextra® were and are adequately described in its FDA-approved prescribing information, which was at all times adequate and comported with applicable standards of care and law. Defendant further states that Bextra® was and is safe and effective when used in accordance with its FDA-approved prescribing information.

RESPONSE TO UNNUMBERED "WHEREFORE" PARAGRAPH IN COUNT EIGHT

Defendant denies that there is any legal or factual basis which entitles Plaintiff to recover any of the relief requested in the prayer for relief in the unnumbered "WHEREFORE" paragraph in Count Eight of the Complaint.

RESPONSE UNNUMBERED "WHEREFORE" PARAGRAPH IN PRAYER FOR RELIEF

Defendant denies that there is any legal or factual basis which entitles Plaintiff to recover any of the relief requested in the prayer for relief in the unnumbered "WHEREFORE" paragraph in Prayer for Relief of the Complaint, including subparts (a) through (e).

ADDITIONAL DEFENSES

By asserting the following affirmative defenses, Defendant does not allege or admit it has the burden of proof and/or the burden of persuasion with respect to any of these matters:

1. The Complaint fails to state a claim upon which relief can be granted.

2. Plaintiff's claims are barred by the applicable statutes of limitations and/or repose.

3. The methods, standards, and techniques utilized with respect to the manufacture, design, and marketing of Bextra®, if any, used in this case, included adequate warnings and instructions with respect to the product's use in the package insert and other literature, and conformed to the generally recognized, reasonably available, and reliable state of the knowledge at the time the product was marketed.

4. The claims asserted in the Complaint are barred because Bextra® was designed, tested, manufactured and labeled in accordance with the state-of-the art industry standards existing at the time of the sale.

5. The claims asserted in the Complaint are barred in whole or in part by the "learned intermediary" doctrine.

6. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same was caused by operation of nature or other supervening or intervening conduct of persons other than Defendant, and for whose conduct Defendant is not responsible, or with whom Defendant has no legal relation or legal duty to control.

7. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same was caused by the negligence of Plaintiff in failing to exercise due and

proper care under the existing circumstances and conditions, and Plaintiff's damages, if any, are barred or reduced by the doctrines of contributory or comparative negligence.

8. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same was caused by the unforeseeable alterations, improper handling, or other unforeseeable misuse of Bextra® by persons other than Defendant or persons acting on its behalf.

9. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® was not unreasonably dangerous or defective, was suitable for the purpose for which it was intended, and was distributed with adequate and sufficient warnings.

10. Plaintiff's claims are barred, in whole or in part, by the equitable doctrines of laches, waiver, and/or estoppel.

11. Plaintiff's claims are barred because his injuries, if any, were the result of pre-existing and/or unrelated medical, genetic and/or environmental conditions, diseases or illnesses, subsequent medical conditions or natural courses of conditions, and were independent of or far removed from Defendant's conduct.

12. If Plaintiff sustained any injuries or incurred any losses or damages as alleged in the Complaint, the same was caused by unforeseeable idiosyncratic reactions of Plaintiff.

13. Plaintiff's claims are barred by the doctrines contained in the Restatement (Second) Torts §402(a), Comment j, Restatement (Second) Torts §402(a), Comment k, and/or Restatement (Third) of Torts: Products Liability §§ 4 *et. seq.* and 6.

14. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® did not proximately cause injuries or damages to Plaintiff.

15. To the extent that Plaintiff's claims are based on a theory providing for liability without proof of causation, the claims violate Defendant's rights under the United States Constitution.

16. The claims asserted in the Complaint are barred, in whole or in part, because Plaintiff did not incur any ascertainable losses as a result of Defendant's conduct.

17. The claims asserted in the Complaint are barred, in whole or in part, because the manufacturing, labeling, packaging, and any advertising of the product complied with the applicable codes, standards and regulations established, adopted, promulgated or approved by any applicable regulatory body, including but not limited to the United States, any state, and any agency thereof.

18. The claims are barred, in whole or in part, because the advertisements, if any, and labeling with respect to Bextra® were not false or misleading, and therefore constitute protected commercial speech under the applicable provisions of the United States Constitution.

19. The claims must be dismissed because Plaintiff would have taken Bextra® even if the product labeling contained the information that Plaintiff contends should have been provided.

20. The claims asserted in the Complaint are barred because the utility of Bextra® outweighed its risks.

21. Plaintiff's fraud-based claims, if any, are not stated with particularity as required by Rule 9 of the Federal Rules of Civil Procedure.

22. The claims asserted in the Complaint are barred, in whole or in part, because Defendant did not violate the Illinois Consumer Fraud and Deceptive Business Practices Act, 815 ILCS 505/1 *et seq*., and/or this Act is not applicable to this matter and/or to this Plaintiff.

23. Plaintiff's damages if any, are limited by Plaintiff's failure to mitigate.

24. Plaintiff's damages, if any, are barred or limited by the payments received from collateral sources.

25. The liability of Defendant, if any, can only be determined after the percentages of responsibility of all persons who caused or contributed toward Plaintiff's alleged damages, if any, are determined. Defendant seeks an adjudication of the percentage of fault of the claimant and each and every other person whose fault could have contributed to the alleged injuries and damages, if any, of Plaintiff.

26. Defendant is entitled to credit for any settlement of claims for alleged injuries and damages made by Plaintiff with any other defendant or other person or entity.

27. Plaintiff's claims are preempted by federal law and regulations, including but not limited to the Federal Food, Drug & Cosmetic Act, 21 U.S.C. §301 *et. Seq.,* the regulations promulgated thereunder, and the United States Constitution, Article IV, clause 2.

28. Plaintiff's claims are barred, in whole or in part, by the doctrine of abstention in that the common law gives deference to discretionary actions by the United States Food and Drug Administration under the Federal Food, Drug, and Cosmetic Act.

29. The claims asserted in the Complaint are barred, in whole or in part, by the doctrines of primary jurisdiction and exhaustion of administrative remedies, because the FDA has exclusive or primary jurisdiction over the matters asserted in the Complaint.

30. The claims asserted in the Complaint are barred, in whole or in part, because Bextra® is comprehensively regulated by the FDA pursuant to the Federal Food, Drug & Cosmetic Act ("FDCA"), 21 U.S.C. §§ 301 *et seq*., and regulations promulgated thereunder, and

Plaintiff's claims conflict with the FDCA, with the regulations promulgated by FDA to implement the FDCA, with the purposes and objectives of the FDCA and FDA's implementing regulations, and with the specific determinations by FDA specifying the language that should be used in the labeling accompanying Bextra®. Accordingly, Plaintiff's claims are preempted by the supremacy clause of the United States Constitution, Article VI, clause 2, and the laws of the United States.

31. If Plaintiff sustained injuries or losses as alleged in the Complaint, such injuries or losses were only so sustained after Plaintiff knowingly, voluntarily, and willfully assumed the risk of any injury as the result of the consumption of, administration of, or exposure to any drug or pharmaceutical preparation allegedly sold by Defendant or other sellers.

32. If Plaintiff sustained injuries or losses as alleged in the Complaint, upon information and belief, such injuries and losses were caused by the actions of persons not having real or apparent authority to take said actions on behalf of Defendant and over whom Defendant had no control and for whom Defendant may not be held accountable.

33. Plaintiff's claims are barred in whole or in part because Bextra® "provides net benefits for a class of patients" within the meaning of Comment f to Section 6 of the Restatement (Third) of Torts: Product Liability.

34. Plaintiff's claims are barred, in whole or in part, by the doctrine of accord and satisfaction.

35. Plaintiff's claims are barred in whole or part because they have been filed in an improper venue.

36. Defendant reserves the right to assert any additional defense which might come to its attention or might be developed during the pendency of this action.

JURY DEMAND

Defendant hereby demands a jury trial on all issues so triable in this action.

By: /s/ Robert H. Shultz, Jr.
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PROOF OF SERVICE

I hereby certify that on April 18, 2007, I electronically filed the foregoing document with the Clerk of the Court using CM/ECF system which will send notification of such filing to the following:

Aaron K. Dickey Aaron@gmhalaw.com

/s/ Robert H. Shultz, Jr.
HEYL, ROYSTER, VOELKER & ALLEN